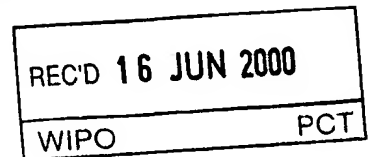


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התקן לאיחוי שברי צוואר הירך
(ניוסף לבקשה No. 129903)

(בְּעִבְרִית)
(Hebrew)

OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER IN COMPRESSION THE PARTS OF A FRACTURED FEMUR NECK

(באנגליש)
(English)

(Addition to the patent application No. 129903)

heretofore apply for a patent to be granted to me in respect thereof.

סבקש בזאת כי ינתן לי עליה פהגם

* בקשת חלוקה — Application of Division		* בקשת סטנט מוסף — Application for Patent Addition		* דרישה ריין קדימה Priority Claim	
מבקשת פטנט from Application		* לבקשה/לפטנט to Patent/Appl.		מספר/סימן Number/Mark	תאריך Date
מס' No. dated		מס' No. dated			
* יסודי כח: כללי / מיוחד — רצוף בזה / עוד יוגש P.O.A.: general/individual-attached/to be filed later- הוגש בענין filed in case					
הכען למסירת פטנטים בישראל Address for Service in Israel 64, Hashahar Str., Raanana 43565, Israel					
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התקן לאיחוי שברי צוואר הירך

**OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER
IN COMPRESSION THE PARTS OF A FRACTURED
FEMUR NECK**

Inventors: Ahi-Izil IZILOV
 Gennady NICKELSHPUR
 Zeev AHARONSON

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**OSTEOSYNTHESIS DEVICE
FOR HOLDING TOGETHER IN COMPRESSION THE
PARTS OF A FRACTURED FEMUR NECK**

The present invention is an addition to the invention according to
Israel patent application # 129903, 11.05.1999.

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OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER IN COMPRESSION THE PARTS OF A FRACTURED FEMUR NECK

FIELD AND BACKGROUND OF THE INVENTION

The invention relates to medicine and in particular to devices applied for osteosynthesis at femur neck fractures.

The present invention is an addition to the invention according to Israel patent application # 129903, 11.05.1999.

The FIG.1 drawing illustrates terms used here to define the location of femur parts and kinds of femur neck fractures. This drawing shows femur 11 (Hip bone), femur head 12 (Capitulum), femur neck 13 (Collum), characteristic femur areas- Trochanter major 14, Trochanter minor 15, Undertrochanter area 16, so-called Cortical layer 17 and Diaphysis 18. For better understanding of the invention subject-matter two areas of the hip bone are defined: the

proximal area P and distal area D.

Femur neck fractures (FIG.1) are divided into medial fractures and lateral fractures. Medial fractures include subcapital fracture 21, transcervical fracture 23 and basal fracture 25. Lateral fractures include transtrochanter fracture 27, intertrochanter fracture 29 and undertrochanter fracture 30.

Dotted lines 31, 33, 35, 37 schematically show the relation of various anthropometric dimensions of femur neck in different patients. Dotted axial line 38 shows the approximal location of longitudinal axis of the osteosynthesis screw after setting it inside the femur neck.

The problem of treating femur neck fractures is of great social importance, especially in geriatrics. This kind of injuries is most frequent with elderly people. The number of such injuries essentially increases towards the age of 70 and is often caused by a relatively light trauma, non-coordinated movements, sharp turns, walking, going upstairs, lifting and carrying heavy loads, as due to senile osteoporosis characteristic of elderly people the bones become more brittle and fragile. Unfortunately femur neck fractures, especially subcapital fractures, unite badly, so that for elderly people they often become a fatal disaster.

Only in USA medical statistics estimates 250 thousand femur neck

fractures annually. 20% of victims die within a year. After a year's treatment 15-20% of patients are still in need of care, with 50% of them aftereffects are found. \$ 7 billions are annually spent in USA to provide medical care of patients with femur neck fractures (H.W. Wahner, 1987).

--- The vast majority of elderly people with femur neck fractures have age changes of different prominence and suffer from internal diseases. They have limited reserve and protective forces of the organism. Even after correct and timely osteosynthesis with elderly and old people nonunion of femur neck fractures and development of femur head necrosis occurs nearly in 30 % of patients (A.V.Kaplan, 1979).

Most of patients in this age group suffer from pronounced osteoporosis. Therefore stops are badly fixed in a porous bone. This often results in a second displacement and nonunion of bone fragments. In this age subcapital femur neck fractures occur most frequently, and fragments fixing at osteoporosis appears to be inadequately stable. Therefore recently at femur neck fractures with elderly people endoprosthesis is performed. Total replacement of the thigh joint in such patients is carried out very seldom because of its traumatability, hemophilia as well as of osteoporosis and essential operational risk. Endoprosthesis at femur neck fractures is performed more often though there is a great number of contraindications to

its application. It would not be correct to apply it at all femur neck fractures in elderly patients.

Closed osteosynthesis by means of a special device to treat such fractures would be the best way for elderly people. Even in case of its unfavorable outcome (fracture nonunion) in distant future it may provide sufficient existence of the patient in the immediate future.

Numerous devices have been developed world over for closed osteosynthesis at femur neck fractures, such as Compression Richard screw system by "Richards Manufacturing Co. Inc.", Memphis, Tennessee, USA. see U.S. Pat. No. 4,095,591.

The compression screw system includes an extension is provided for being nonrotatably fixed to a lag screw that is to be anchored to the head of a femur or other bone in a manner so as to allow compression to be applied to a fracture. The extension extends outward of the bone when attached to the lag screw is anchored to the bone to allow a compression plate to be easily positioned thereof. The cross section of the extension is substantially the same as the cross section of the lag screw to allow the compression plate to be easily and quickly passed onto the lag screw from the extension once the compression plate has been positioned on the extension.

The drawbacks of Richards system, in our opinion, are as follows: a) the bone tissue of the femur head is drilled out over the whole duct length whereby bone tissue (trabeculae) and endosteum are essentially destructed. the blood supply which is already insufficient is affected; b) the design of the introduced rod and its inadequately effective thread do not provide a stable compression connection of bone parts. At best bone fragments simply come in contact without a stable mutual fixation. Micromobility of bone fragments is as well possible. c) to position Richards system it is necessary to make a large cut in the femur muscular tissues to locate a compression plate.

Hence a conclusion may be made that Richards system is inefficient for the treatment of femur neck fractures, especially of subcapital fractures which simply do not unite in most cases.

Since the publication of U.S. Pat. No. 4,095,591 and up to now numerous improvements of Richards system have been made in USA and other countries, see U.S. Pat. No. 4,236,512; 4,432,358; 4,791,918; 4,794,919; 4,964,403; 5,871,485 (1978-1999), Patent of Israel No. 54025 (1978).

However all the above mentioned devices have the drawbacks of Richards system- high traumatability of the femur bone and tissues and

inadequate efficiency for the treatment of femur neck fractures, such as medial fractures. The application of these devices for the treatment of subcapital fractures is simply unsuitable.

There are also known devices developed by "Howmedica International Inc." (see U.S. Pat. No. 5, 176, 681), "Smith & Nephew Richards Inc." (U.S. Pat. No. 5, 167, 663 and EP 0441577), "Endocare AG" (U.S. Pat. No. 5, 713, 902). These devices comprise a rod introduced inside the hip bone and a screw attached to this rod to fix the femur neck. The devices are unwieldy, may cause traumas to the patient, and their efficacy is on the level of the Richard system device .

There is further known an "Osteosynthesis device" disclosed in U.S. Pat. No. 5,437,674. An osteosynthesis device including a screw whose tip is pyramidal or conical and whose body is provided, at a distal end thereof, with an outside thread, wherein the head of the screw has a plurality of foldable small wings integral with the body and wherein the screw has a device for folding the small wings. The device is useful particularly for fractures of the scaphoid, of the medial malleolus, Garden fractures 1 and 2 of the neck of the femur, pertrochanterian fractures of the femur, and generally, for fractures of small bones, and for putting in place hip or

shoulder stops.

However this device is also inadequately efficient for the treatment of femur neck fractures, such as medial fractures. It cannot be used for the treatment of subcapital fractures.

Closest to the claimed invention is the "Osteosynthesis device for femur neck fractures", USSR Pat. No. 938969. The device comprises a rod with a buttress thread on one end and a hold-down nut on the other end of the rod having an internal thread. There are also provided tabs located in apertures formed in the rod on the side of the hold-down nut and a mechanism for operating the tabs. The mechanism includes a screw disposed in the inner tread of the rod and engaging the tabs.

However this device also has some drawbacks. It is not universal as its design does not allow for the differences in linear femur neck dimensions with different people, different cortical layer thickness in the undertrochanter femur area, and therefore does not provide mobility of the antimigration device, and its anchoring in the bone is not secure enough. Therefore such a device must be manufactured individually for each patient or in series differing in dimensions according to anthropological parameters of different patients.

Besides, the device as it is shown in USSR patent No. 938969 is unsuitable for treating several kinds of lateral fractures, such as undertrochanter fractures, as it is not fully universal for all kinds of femur neck fractures. "Osteosynthesis Device for Holding Together in Compression the Parts of a Fractured Femur Neck", according to Israel Patent Application # 129903, 11.05.1999 is a further development and improvement of the device disclosed in USSR Pat. # 938969 which eliminates part of its drawbacks.

The osteosynthesis device according to Israel patent application # 129903 comprises: a) a screw formed as step-shaped rod, b) a means for imparting rotational movement to the screw, c) antimigration device for anchoring said screw inside the bone, d) hold-down nut. Besides, the osteosynthesis device additionally comprises: e) at least one extension sleeve, f) at least one additional nut.

The osteosynthesis device also includes a strap applied for holding together in compression bone parts solely at lateral femur neck fractures and positioned on the femur outer surface near the shin undertrochanter area, the strap being provided with means for its rigid connection with the screw distal end. The strap consists at least of two parts hinged together, and the inner surfaces of these parts are opposite to the adjacent outer surface of the

femur undertrochanter area.

A drawback of the device disclosed in Israel patent application # 129903 is that it is unsuitable for treating several kinds of lateral fractures, such as undertrochanter fractures as it is not fully universal for treating all kinds of femur neck fractures.

An object of the present invention is to provide a fully universal and simple device for compression treatment of all kinds of femur neck fractures including medial fractures, including both subcapital fractures and lateral fractures, such as undertrochanter, intertrochanter and transtrochanter fractures.

Another object of the present invention is to provide more reliable anchoring of the osteosynthesis device in the bone at all kinds of femur neck fractures and reliable compression union of bone parts in patients with different anthropometric dimensions of femur neck.

SUMMARY OF THE INVENTION

The present invention is an addition to the invention according to Israel patent application # 129903, 11.05.1999.

According to the present invention there is proposed an osteosynthesis device for holding together in compression bone parts at all

femur neck fractures, including undertrochanter, intertrochanter and transtrochanter lateral fractures comprising: a) a screw formed as a step-shaped rod, b) an antimigration device for anchoring the screw inside the bone, c) a hold-down nut. Besides, the claimed device additionally comprises: d) at least one extension sleeve, e) at least one additional nut.

The step-shaped rod has a proximal end with a buttress self-tapping thread and a distal end with external thread and an internal axial cavity which is provided with internal thread on its distal end and is associated with the external cylindrical surface of the rod via several longitudinal apertures evenly arranged on this surface and parallel to the generatrix of this surface. The outer diameter of the rod distal end matches the outer diameter of the buttress self-tapping thread on its proximal end.

The antimigration device for anchoring the screw inside the bone is located in the internal axial cavity and comprises a collet chuck with release tabs disposed in the apertures. The collet chuck comprises several levers connected on their proximal ends to define a ring having an inner axial threaded hole, the levers being provided with release tabs on their distal ends.

There is also a mechanism for reciprocal movement of the collet chuck inside the axial cavity and a mechanism for release tabs operation.

The osteosynthesis device includes a hold-down nut located on the rod distal end and movable along its external thread, the nut having a rounded proximal butt and means for registration with a special wrench on the distal butt of the nut.

There is at least one extension sleeve with a through-axial hole, a means for connection with the rod distal end and with the external thread. At least one additional nut is located on the external thread of the extension sleeve and has a rounded proximal butt and means on its distal butt to register with wrench.

In the claimed device the screw is a step-shaped rod having an integral (solid) proximal end with a buttress self-tapping thread and a butt shaped as a cone. This screw may be also shaped as a step-shaped rod with a through axial hole and proximal end with a buttress self-tapping thread and a butt shaped as a truncated cone.

The screw proximal end is provided with external buttress self-tapping thread the ends of which are formed as a screw tap, and in the middle of the threaded portion and in the body of the screw proximal end there are grooves for receiving bone chips generated while the screw is being positioned.

The mechanism for reciprocal movement of the collet chuck inside the axial cavity comprises a threaded axial stud reciprocable in the threaded axial hole of this collet chuck, the stud having a lateral slot on its distal end.

The mechanism for release tabs operation comprises a release screw having a conical proximal end and a distal end—with a lateral slot. This release screw is placed in the internal thread of the axial cavity to reciprocate and engage with release tabs of the collet chuck.

The osteosynthesis device is characterized in that to hold together in compression bone parts solely in lateral femur neck fractures it also comprises a strap mounted on the external surface of the femur undertrochanter area, the strap, to be adapted for patients with different anthropometric dimensions of femur neck, consisting of at least two parts connected together within a certain range of angular and/or spatial positions and provided with means for its rigid connection with the femur undertrochanter area and the osteosynthesis screw distal end. The proximal surfaces of said strap parts are opposite to the adjacent external surface of the femur undertrochanter area. At least one of said strap parts is a basic one and rigidly attached, by nails and/or wood screws, to the external surface of the femur undertrochanter area. The second of said strap parts is an intermediate one and is rigidly attached by one end, via a hold-down nut, to

the osteosynthesis screw distal end , and by its second end connected with the strap basic part.

The strap intermediate part is provided on one end with a through hole for rigid connection with said osteosynthesis screw distal end. said hole flaring at its distal end opposite to the rounded proximal butt of the respective hold-down or additional nut.

The basic and intermediate strap parts are rigidly connected together by means of a mechanical detachable joint. This mechanical detachable joint may be a detachable articulated joint. It may be as well a detachable articulated joint and at least one screw joint. Said at least one screw joint may be spring-loaded. Besides, the strap basic and intermediate parts may be connected together via at least two detachable screw joints. In this case one of said strap parts may be female and the other a male one.

The strap intermediate part may be S-shaped in its longitudinal section and have a through longitudinal slot with several holes for fixing said detachable articulated joint in an appropriate position.

Besides, the strap intermediate part may be S-shaped in its longitudinal section and have at least two through holes on opposite ends for rigid attachment of the strap respective end to the osteosynthesis screw distal end.

In another embodiment the strap intermediate part is a male part. S-shaped in its longitudinal section, has means for fixing said detachable articulated joint in a corresponding position, said means including several lateral openings. Besides, it has at least two through holes on opposite ends for rigid connection of said strap to the distal end of said screw for osteosynthesis.

In a still another embodiment said strap basic part is a female part and provided with several openings for fixing the detachable articulated joint of said strap basic and intermediate parts in a corresponding position.

And, at last, said strap intermediate part is C-shaped in its longitudinal section and has a through longitudinal slot which is open on one side and serves to fix the strap intermediate part in a corresponding position relative to its basic part.

The strap basic part is provided with holes for attachment by nails and/or wood screws to the external surface of femur undertrochanter area, said holes being staggered.

BRIEF DESCRIPTION OF THE DRAWINGS

The description of the present invention is accompanied by drawings wherein:

FIG. 1 shows a diagram illustrating kinds of femur neck fractures, terms used to specify location of femur parts as well as relation of different anthropometric femur neck dimensions in different patients.

FIG. 2 shows the most preferable embodiment of the claimed osteosynthesis device with an additional strap.

FIG. 2-a and FIG. 2-b show a proximal end embodiment of the claimed osteosynthesis device as a screw tap.

FIG. 2-c shows an embodiment of the additional strap.

FIG. 2-d, 2-e show longitudinal sections of the additional strap, A - A and B - B respectively.

FIG. 3 shows the additional sleeve and additional nut in longitudinal section.

FIG. 4 shows the preferred embodiment of the claimed osteosynthesis device (longitudinal section) with an additional cylindrical sleeve mounted.

FIG. 5 shows the longitudinal section of the buttress self-tapping thread (view II).

FIG. 6 shows an embodiment of the claimed osteosynthesis device with an additional step-shaped sleeve.

FIG. 7 shows an embodiment of the additional strap including a male basic part and female intermediate part.

FIG. 8 shows the additional strap presented in Fig.7, top view.

FIG. 9 shows the longitudinal section C - C of said strap intermediate part as in Fig.7.

FIG. 10 shows the strap basic part according to Fig. 7.

FIG. 11 shows the section along D - D of the basic part of said strap shown in Fig. 7.

FIG. 12 shows the section along E - E of the intermediate part of the strap shown in Fig. 7.

FIG. 13 shows an embodiment of the additional strap having an S-shaped female intermediate part and a male basic part.

FIG. 14 shows the top view of the additional strap shown in Fig. 13.

FIG. 15 shows the longitudinal section F - F of the intermediate part of strap according to Fig. 13.

FIG. 16 shows the basic part of strap according to Fig. 13.

FIG. 17 shows section along G - G of the basic part of strap shown in Fig. 13.

FIG. 18 shows section along H - H of the intermediate part of strap shown in Fig. 13.

FIG. 19 shows an embodiment of the additional strap as an S-shaped male intermediate part and female basic part.

FIG. 20 shows the top view of the additional strap shown in Fig. 19.

FIG. 21 shows the longitudinal section J - J of the intermediate part of strap according to Fig. 19.

FIG. 22 shows the basic part of strap according to Fig. 19.

FIG. 23 shows the section along K - K of the intermediate part of strap shown in Fig. 19.

FIG. 24 shows the section along L - L of the basic part of strap shown in Fig. 19.

FIG. 25 shows an embodiment of the additional strap as a C-shaped female intermediate part and male basic part.

FIG. 26 shows view III of the additional strap shown in Fig. 25.

FIG. 27 shows the top view of the additional strap shown in Fig. 25.

FIG. 28 shows the longitudinal section M - M of the intermediate part of strap according to Fig. 25.

FIG. 29 shows the basic part of strap according to Fig. 25.

FIG. 30 shows the section along N - N of the intermediate part of strap shown in Fig. 25.

FIG. 31 shows the section along O - O of the basic part of strap shown in Fig. 25.

FIG. 32 shows a diagram of drilling in the hip bone a passage to position the osteosynthesis device.

FIG. 33 shows a diagram of positioning in the hip bone the claimed osteosynthesis device together with an additional strap designed according to the first of the suggested embodiments.

FIG. 34 shows a diagram of positioning in the hip bone the claimed osteosynthesis device together with the additional strap designed according to the second of the claimed embodiments.

FIG. 35 shows a diagram of positioning in the hip bone the suggested osteosynthesis device together with an additional strap designed according to the third of the claimed embodiments.

FIG. 36 shows a diagram of positioning in the hip bone the claimed osteosynthesis device together with an additional strap designed according to the fourth of the suggested embodiments.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to the present invention there is proposed an osteosynthesis device for holding together in compression bone parts for all kinds of femur neck fractures, including undretrochanter, intertrochanter and transtrochanter lateral fractures. This device (see FIG.2) includes: a) a screw **100** formed as a step-shaped rod, b) a slot **102** to impart rotary motion to the screw **100**, c) an antimigration device **104** for anchoring screw **100** inside the bone, d) a hold-down nut **106**. Besides there are (see FIG. 3): e) at least one extension sleeve **108**. and f) at least one additional nut **110**.

In another embodiment the osteosynthesis device set includes beside a screw **100** (see FIG. 2) an additional strap **113** applied to hold together in compression bone parts solely in undertrochanter, intertrochanter and transtrochanter lateral femur neck fractures and mounted on the femur outer surface close to undertrochanter area **16** of the hip bone, strap **113** being rigidly connected with screw **100** distal end. Strap **113** as shown in FIG. 2-c consists of two parts hinged together, the proximal surfaces of these parts are opposite, i.e. concave in relation to the adjacent external surface of femur undertrochanter area (FIG. 2-d, 2-e).

In the embodiment of the osteosynthesis device (see FIG. 4) step-shaped rod 112 has a longitudinal axis 114, a through axial hole 116, a proximal end 118 with a buttress self-tapping thread 120 and a butt 122 shaped as a truncated cone. There is also a distal end 124 with external thread 126 and an internal axial cavity 128 which is provided with internal thread 130 on its distal end 132 and is in open communication with external cylindrical surface 134 of rod 112 via several longitudinal apertures 136 angularly evenly arranged on this surface 134 and parallel to the generatrix of this surface. The outer diameter of rod distal end 124 matches the outer diameter of buttress self-tapping thread 120 on its proximal end 118.

External buttress self-tapping thread 120 (FIG. 2, 2-a, 2-b) has on proximal end 118 of rod 112 ends 138 and 140 which comprise a screw tap, and in the middle of the thread portion and in the body of proximal end 118 of rod 112 there are grooves 142 to receive bone chips. External buttress self-tapping thread 120 in the embodiment of the osteosynthesis device shown in FIG. 4 is shaped likewise.

External buttress self-tapping thread 120 (see FIG. 5) of triangular or trapezoidal cross section has a proximal 158 and distal 160 spiral surface. The thread inner diameter and outer diameter are related approximately as 2 : 3. Proximal spiral surface 158 of thread 120 has a relatively greater area

and is located at an angle to the longitudinal axis of rod 112, and distal spiral surface 160 of rod 112 has a relatively smaller area, is substantially perpendicular to the longitudinal axis of rod 112 and serves as a thrust surface in relation to the bone part in which it is introduced for urging this bone part to come into compression contact with at least one more bone part. Proximal spiral surface 158 of thread 120 has in this case a tilt angle α from approximately 30 to approximately 35 degrees. Distal spiral surface 160 of thread 120 has a tilt angle β from approximately 2 to approximately 4 degrees.

Antimigration device 150 for anchoring screw 100 inside the bone (see FIG. 4) is located in internal axial cavity 128 and comprises a collet chuck 152 and includes several levers 153 with release tabs 154 disposed in apertures 136. Levers 153 are substantially coaxial and connected on their proximal ends to form a ring 155 having an internal threaded axial hole 156.

The osteosynthesis device also includes a hold-down nut 162 located on rod 112 distal end 124 and axially movable along its external thread 126, nut 162 having a rounded proximal butt 164 and recesses 166 for registration with a special wrench on the distal butt of the nut.

Extension sleeve 168 (FIG. 4, 6) is shaped as a cylinder with through axial hole 170 and external thread 172 on the external surface of this

sleeve 168. Extension sleeve 168 is applied when femur neck size in a patient exceeds the average statistic value.

Extension sleeve 168 (see FIG. 6) may have a through axial hole 170 and step-shaped external surface. In this case the step of a smaller diameter has external thread 172 to engage distal end 124 of rod 112, and the step of a greater diameter has external thread 174 which is similar to external thread 126 of rod 112, sleeve 168 being provided with a lateral groove 169 on its free end.

At least one additional nut 176 is located on external thread 172 of extension sleeve 168 and has a rounded proximal butt 178 for better engagement with a recess in bone cortical layer 17, and recesses 180 on its distal butt to match a wrench (see FIG. 4). Additional nut 176 is applied when extension sleeve 168 is shaped as a cylinder. When extension sleeve 168 is step-shaped, hold-down nut 162 is mounted on extension sleeve 168.

The osteosynthesis device (see FIG. 4) includes a mechanism for axial reciprocal movement of collet chuck 152 inside axial cavity 128 and a mechanism for release tabs 154 operation. The mechanism for axial reciprocal movement of collet chuck 152 inside axial cavity 128 is a threaded axial stud 182 reciprocable in threaded axial hole 156 of collet chuck 152, stud 182 being provided with lateral slot 184 on its distal end,

and bearing with its proximal end against the end surface of internal axial cavity 128. The mechanism for release tabs 154 operation is a release screw 186 having a cone 188 on the proximal end and a lateral slot 190 on the distal end. This release screw 186 has an external thread associated with internal thread 130 of internal axial cavity 128 which allows the screw to move axially under control in proximal or distal direction, apply radial force to release tabs 154 of collet chuck 152 and push tabs 154 out of longitudinal apertures 136 and thus apply force to engage tabs 154 with bone tissue to prevent migration of the claimed osteosynthesis device.

As already mentioned above, the osteosynthesis device set includes, beside screw 100, strap 113 mounted on the external surface of the femur undertrochanter area.

According to the present invention several embodiments of strap 113 are suggested.

According to the first embodiment shown in FIG. 7 strap 200 includes, to adjust to patients with different anthropometric dimensions of the femur neck, at least two parts, basic 202 and intermediate 204 rigidly

connected together within a certain range of angular and/or spatial positions. The basic part of strap 202 is rigidly attached, by means of nails and/or wood screws, to the outer surface of the femur undertrochanter area 16. Intermediate part 204 of strap 200 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100, and by its second end connected with basic part 202 of strap 200.

Intermediate part 204 of strap 200 (FIG. 8, 9) is provided on one its end with through hole 206 for rigid connection to the distal end of osteosynthesis screw 100. This hole has a flare 208 near its distal end the form of which is opposite in relation to the rounded proximal butt of respective hold-down nut 162 or additional nut 176.

Basic part 202 of strap 200 in this embodiment is female and intermediate part 204 male (FIG. 7). Proximal surfaces, 210 and 212 respectively, of said strap parts are opposite in relation to the adjacent external surface of femur undertrochanter area 16 (FIG. 8, 9).

Basic part 202 and intermediate part 204 of strap 200 are rigidly connected together by a mechanical detachable joint. In this strap embodiment this mechanical detachable joint is a detachable articulated joint 214 and at least one screw joint 216. This screw joint 216 is spring-loaded.

According to the second embodiment shown in FIG. 13 strap 220 consists, to suit patients with different anthropological dimensions of femur neck, at least of two parts, basic 222 and intermediate 224 rigidly connected together within a certain range of angular and/or spatial positions. Strap basic part 222 is rigidly attached, by means of nails and/or wood screws, to the external surface of femur undertrochanter area 16. Intermediate part 224 of strap 220 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100, and by its second end connected with basic part 222 of strap 220.

Intermediate part 224 of strap 200 (FIG. 14, 15) is provided on one end with through hole 226 for rigid attachment to the distal end of osteosynthesis screw 100. This hole 226 has a flare 228 at its distal end the form of which is opposite in relation to the rounded proximal butt of respective hold-down nut 162 or additional nut 176.

Basic part 222 of strap 220 in this embodiment is male, and intermediate part 224 female (FIG. 13, 14, 15). Proximal surfaces, 230 and 232 respectively (FIG. 17, 18), of said strap parts, 222 and 224, are opposite in relation to the adjacent external surface of femur undertrochanter area 16 (FIG. 9). Besides, basic 222 and intermediate 224 parts of strap 220 may be connected together by means of two detachable screw joints, 234 and 236

respectively (FIG. 14).

Intermediate part 224 of strap 220 has in its longitudinal section an S-shape and a through longitudinal slot 238 with several holes 239 for fixing in an appropriate position detachable screw articulated joint 234 (FIG. 13, 15).

According to the third embodiment shown in FIG. 19 strap 240 consists, to suit patients with different anthropometric dimensions of femur neck, of at least two parts, basic 242 and intermediate 244 rigidly connected together within a certain range of angular and/or spatial positions. The basic part of strap 242 is rigidly attached, by means of nail and/or wood screws, to the external surface of the femur undertrochanter area 16. Intermediate part 244 of strap 240 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100, and by its second end attached to basic part 242 of strap 240.

Intermediate part 244 of strap 240 (FIG. 20, 21) is provided on one its end with a through opening 246 for rigid attachment to the distal end of osteosynthesis screw 100. This opening 246 has a flare 248 at its distal end the form of which is opposite in relation to the rounded proximal butt of respective hold-down nut 162 or additional nut 176.

In this embodiment basic part 242 of strap 240 is female and

intermediate part 244 male (FIG. 19). Proximal surfaces, 250 and 252 respectively, of mentioned strap parts, 242 and 244, are opposite in relation to the adjacent external surface of the femur undertrochanter area 16 (FIG. 23, 24).

Besides, intermediate part 244 of strap 240 has in its longitudinal section an S-shape and at least two through openings 246 on opposite ends for rigid attachment of a respective end of strap 240 to the distal end of osteosynthesis screw 100.

Finally, in this embodiment of strap 240 its intermediate part 244 is male, has in its longitudinal section an S-shape, and means for fixing in an appropriate position the detachable articulated joint, these means including several longitudinal apertures 254 (FIG. 21) and screws 255.

Basic part 242 of strap 240 is female and provided with several openings for fixing in appropriate position the detachable articulated joint of basic 242 and intermediate 244 parts of strap 240.

Finally, according to the fourth embodiment of strap 260 (FIG. 25) it consists, to suit patients with different anthropometric dimensions of femur neck, at least of two parts, basic 262 and intermediate 264 rigidly connected together within a certain range of angular and/or spatial positions.

Basic part 262 of strap 260 is rigidly attached, by means of nails and/or wood screws, to the external surface of femur undertrochanter area 16 (FIG. 27). Intermediate part 264 of strap 260 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100, and by its second end connected with basic part 262 of strap 260.

Intermediate part 264 of strap 260 (FIG. 25, 27) is provided on one its end with through opening 266 for rigid attachment to the distal end of osteosynthesis screw 100. This opening 266 has a flare 268 at its distal end the form of which is opposite in relation to the rounded proximal butt of respective hold-down nut 162 or additional nut 176.

In this embodiment basic part 262 of strap 260 is male and intermediate part 264 female (FIG. 25).

Proximal surfaces, 270 and 272 respectively, of these strap parts, 262 and 264, are opposite to the adjacent external surface of femur undertrochanter area (FIG. 30, 31).

Intermediate part 264 of strap 260 has in its longitudinal section a C-shape and through longitudinal T-shaped slot 274 open from one end and serving to fix intermediate part 264 of strap 260 in appropriate position in relation to its basic part 262 (FIG. 25, 26, 27, 28) by means of screws 276.

Basic part 262 of strap 260 is provided with openings 276 for

attachment, by means of nails and/or wood screws, to the external surface of femur undertrochanter area, these openings 276 are staggered (FIG. 29).

The claimed device is applied as follows.

Fracture fragments are reponed under periodic X-ray observation. A 3-4 cm long external cut is made to expose femur undertrochanter area 16 . In the spot wherein Trochanter major changes to femur Diafiz 18 a twist drill needle is passed, by means of a drill, in direction of the femur neck axis. The bone cortical layer 17, 2 cm in diameter, is removed by a chisel around the needle end. Then, under periodic X-ray control, a hole is drilled out (FIG. 32). The drilling depth is a little greater than the length of screw 100.

Then driving of screw 100 (FIG. 33) is started. Screw 100 is passed through this part of the bone hole which has been drilled out by the drill of greater diameter, and then driven in the remaining part of this hole using end 138 of external buttress self-tapping thread 120 (see FIG. 33) as a screw tap.

Bone chips generated in the process fill grooves 142 in the middle of the threaded portion and in the body of proximal end 118 of rod 112. Once screw 100 has been driven, the holder is separated from screw 100, and inside axial cavity 128 of screw 100 antimigration device 150 is inserted.

Once screw 100 has been mounted, femur head 12 and neck 13 are made coincident and held down in compression. To this end a special wrench is put over hold-down nut 162, by matching wrench pins with recesses 166 on butt of hold-down nut 162. Then, by turning the special wrench, nut 162 is held down until it is against the bone cortical surface 17. The tightening of nut 162 by means of buttress thread 120 causes compression of the bone endosteum. The femur head 12 and neck 13 are made coincident and pressed together tightly.

If the length of screw 100 is inadequate, it can be increased by using one or several extension sleeves 168 (see FIG. 6). Sleeve 168 is partly screwed in along thread 130 into internal axial cavity 128 of screw 100. In this case, to hold together femur head 12 and neck 13, instead of hold-down nut 162, additional nut 176 is used. Nut 176 is screwed up by means of the same special wrench.

On making the bone parts coincident in compression, antimigration device 150 (see FIG. 33) is positioned in the desired place and fixed. To position antimigration device 150 in the desired place threaded axial stud 182 is turned. Therewith collet chuck 152 of antimigration device 150 advances along internal axial cavity 128 (under periodic X-ray control) until

the ends of its release tabs 154 come into the necessary position inside the bone, near cortical layer 17. Then release tabs 154 are drawn aside and extended from apertures 136 by means of release screw 186 moved along thread 130. Thereby antimigration device 150 is fixed in the desired position and a paddle system is formed to hold screw 100 inside the bone and exclude mobility and rotation of bone fragments.

Solely in treating lateral undertrochanter, intertrochanter and transtrochanter fractures of femur neck it is possible to apply strap 113, which is placed on the femur external surface near undertrochanter area 16 (see FIG. 33). Schematically it is performed as follows. Screw 100 is set as described above, bone parts are brought into coincidence in compression by tightening hold-down nut 162, antimigration device 150 is set in necessary position and fixed. Then this hold-down nut 162 is unscrewed, strap 113 is set onto screw 100, thereafter hold-down nut 162 is screwed up again to rigidly connect strap 113 with the distal end of screw 100. In this case strap 100 additionally serves as a washer under hold-down nut 162.

More particularly, **setting of screw 100 and an additional strap may be shown by example of the first embodiment of strap 200 (FIG. 33).** At the initial stage screw 100 is set as described above.

Then setting of strap 200 is started (FIG. 33). First, intermediate part 204 of strap 200 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100. Then basic part 202 of strap 200 is attached to the second end of intermediate part 204. To suit patients with different anthropometric dimensions of femur neck, both parts of strap 200, basic 202 and intermediate 204 matched within a certain range of angular and/or spatial positions by detachable articulated joint 214 and screw joint 216, and this is performed until strap 200 tightly fits to femur undertrochanter area. Thereafter basic 202 and intermediate 204 parts of strap 200 are rigidly connected together and fixed in this position by screw 216. Then basic part 202 of strap 200 is rigidly attached, by means of nails and/or wood screws to the external surface of femur undertrochanter area 16 (FIG. 33). The mentioned staggered openings 206 (FIG. 10) provide more reliable attachment of basic part 202 of strap 200 to femur undertrochanter area 16.

Proximal surfaces, 210 and 212 respectively, of these parts of strap 200, 202 and 204 respectively, are opposite in relation to the adjacent external surface of femur undertrochanter area 16 (FIG. 33). Thereby there is provided a more tight contact of proximal surfaces, 210 and 212, of these strap parts 202 and 204 with the adjacent external surface of femur

undertrochanter area 16.

Setting of the strap designed according to the second embodiment is performed likewise (FIG. 34). At the first stage screw 100 is set as described above.

Then setting of strap 220 is started. First, intermediate part 224 of strap 220 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100. Then basic part 222 of strap 220 is attached to the second end of intermediate part 224. To suit patients with different anthropometric dimensions of femur neck, both parts of strap 220, basic 222 and intermediate 224, are matched within a certain range of angular and/or spatial positions by means of two detachable screw joints 234 and 236 and this is performed until strap 220 tightly fits to femur undertrochanter area 16. Thereafter basic 222 and intermediate 224 parts of strap 220 are rigidly connected together and fixed in this position by screws 234 and 236 then basic part 222 of strap 220 is rigidly attached, by means of nails and/or wood screws, to the external surface of femur undertrochanter area 16 (FIG. 34). The above mentioned staggered openings 222 (FIG. 16) provide more reliable attachment of basic part 222 of strap 220 to the femur undertrochanter area 16.

Proximal surfaces, 230 and 232 respectively, of said parts of strap 220, 222 and 224 respectively, are opposite in relation to the adjacent external surface of femur undertrochanter area 16 (FIG. 34). Thereby there is provided a more tight contact of proximal surfaces, 230 and 232 respectively, of said strap parts 222 and 224 with the adjacent external surface of femur undertrochanter area 16.

Setting of the strap of the third embodiment is performed likewise (FIG. 35). At the first stage screw 100 is positioned as described above.

Then setting of strap 240 is started. First, intermediate part 224 of strap 240 is rigidly attached by one its end, by means of hold-down nut 162 or additional nut 176, to the distal end of screw 100. Thereafter basic part 242 of strap 260 is attached to the second end of intermediate part 244. For application in patients with different anthropometric dimensions of femur neck, both parts of strap 240, basic 242 and intermediate 244, are matched within a certain range of angular and/or spatial positions by screws 255 and openings 254, and this is performed until strap 240 tightly fits to femur undertrochanter area 16. The design of strap 244 intermediate part allows, when necessary, to turn it over and connect by the other end to the distal end of screw 100 to achieve tighter fit to femur undertrochanter area 16. Next basic 242 and intermediate 244 parts of strap 240 are rigidly connected

together and fixed in this position by screws 255. Thereupon basic part 242 of strap 240 is rigidly attached, by means of nails and/or wood screws, to the external surface of femur undertrochanter area 16 (FIG. 35). Said staggered openings in basic part 242 (FIG. 20) provide more reliable attachment of basic part 242 of strap 240 to femur undertrochanter area 16.

Proximal surfaces, 250 and 252 respectively, of said parts of strap 240, 242 and 244 respectively, are opposite to the adjacent external surface of femur undertrochanter area 16 (FIG. 35). This provides tighter contact of proximal surfaces, 250 and 252 respectively, of said strap parts 242 and 244 with the adjacent external surface of femur undertrochanter area 16.

Setting of screw 100 and additional strap 260 of the fourth embodiment (FIG. 36) is performed likewise. At the first stage screw 100 is positioned as described above. Then setting of strap 260 is started. First, intermediate part 264 of strap 260 is rigidly connected by one its end, by means of hold-down nut 162 or additional nut 176, to distal end of screw 100. Thereafter basic part 262 of strap 260 is attached to the second end of intermediate part 264. To suit patients with different anthropometric dimensions of femur neck, both parts of strap 260, basic 262 and intermediate 264 are matched within a certain range of angular and/or spatial

positions by T-shaped slot 272 and screws 276, and this is performed until strap 260 fits tightly to femur undertrochanter area 16. Then basic 262 and intermediate 264 parts of strap 260 are rigidly connected together and fixed in this position by screws 276. Next basic part 262 of strap 260 is rigidly attached by means of nails and/or wood screws, to the external surface of femur undertrochanter area 16 (FIG. 33). Said staggered openings 276 (FIG. 29) provide more reliable attachment of basic part 262 of strap 260 to femur undertrochanter area 16.

Proximal surfaces, 270 and 272 respectively, of said parts of strap 260, 262 and 264 respectively, are opposite in relation to the adjacent external surface of femur undertrochanter area (FIG. 36). This provides tighter contact of proximal surfaces, 270 and 272 respectively, of said strap parts 262 and 264 with the adjacent external surface of femur undertrochanter area 16. Said staggered openings 276 (FIG. 29) provide more reliable attachment of basic part 262 of strap 260 to femur undertrochanter area 16.

Screw 100 in combination with hold-down nut 162, antimigration device 150 and strap 260 form an integral spatial system which provides reliable compression fixing of bone fragments at any kind of femur neck.

fractures, including undertrochanter, intertrochanter and transtrochanter lateral fractures. therefore the claimed device is a universal means for reliable osteosynthesis of all known femur neck fractures.

If necessary, screw **100** may be removed after the union of femur neck parts. For this purpose the above procedure is carried out in the reverse order. First release screw **186** is removed, then, by turning axial threaded stud **182**, collet chuck **152** of antimigration device **150** is moved inside axial cavity **128**, opening thereby its release tabs **154** and retracting them into apertures **136**. Thereafter, by means of special wrench hold-down nut **162** is unscrewed and strap is removed (if it has been mounted). This is performed in an order reverse to that of setting the screw. Thereupon screw **100** is removed from the femur neck. To facilitate the removal of screw **100**, end **140** of its self-tapping buttress thread **120** is formed as a screw tap. Such a design of thread **120** allows to use its end **140** for cutting off excrescences of bone tissue which have grown in the hole channel in the femur neck wherefrom screw **100** is removed. The removal of screw **100** is performed under periodic X-ray control.

Application of the claimed device for femur neck osteosynthesis provides accurate and secure matching of bone fragments in compression during the whole period of the fracture union. Besides the duration of surgical interference is essentially reduced and traumatization of endosteum and bone marrow of the femur head and neck is insignificant. The claimed device is suitable for compression treatment of all kinds of femur neck fractures, including medial fractures, such as subcapital fracture and lateral fractures, including undertrochanter fractures. And finally the claimed device is adapted to any anthropological parameters of different patients, easily mounted and, when necessary, easily removed.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

CLAIMS

We claim:

1. An osteosynthesis device for holding together in compression bone parts at all kinds of femur neck fractures, including undertrochanter, intertrochanter and transtrochanter lateral fractures comprising:

a) an osteosynthesis screw designed as a step-shaped rod having a proximal end with buttress self-tapping thread, and a distal end with external thread and internal axial cavity associated with a cylindrical external surface of said rod via several longitudinal apertures evenly arranged on this surface, the outer diameter of said rod distal end corresponding to the outer diameter of a buttress self-tapping thread on the proximal end of said rod;

b) an antimigration device for anchoring said screw inside the bone located in said internal axial cavity and comprising a collet chuck with release tabs disposed in said apertures, and a mechanism for reciprocal movement of the collet chuck inside said axial cavity and a mechanism for release tabs operation;

c) a hold-down nut located on said rod distal end and movable axially along its external thread, said nut having a rounded proximal butt and means for registration with a special wrench on the distal butt of the nut; said osteosynthesis device characterized in that for holding together in compression bone parts solely at lateral fractures of femur neck it also comprises a strap which is set on the external surface of the femur undertrochanter area, said strap, to suit patients with different anthropologic dimensions of femur neck, consists at least of two parts rigidly connected together within a certain range of angular and/or spatial positions and is provided with means for its rigid connection with the undertrochanter area of femur neck and distal end of said osteosynthesis screw.

2. Osteosynthesis device for holding together in compression the parts of a fractured femur neck according to claim 1, which, in order to treat patients with a femur neck size exceeding the average statistic value, additionally includes:

d) at least one extension sleeve having a through axial hole, a means for connection with said osteosynthesis screw distal end, and external thread;

e) at least one additional nut located on the external thread of said at least one extension sleeve and having a rounded proximal butt and means for registration with a wrench on its distal butt.

3. A device according to claim 1 wherein said strap set on the external surface of the femur undertrochanter area consists at least of two parts rigidly connected together within a certain range of angular and/or spatial positions, the proximal surfaces of said parts being opposite to the adjacent external surface of femur undertrochanter area.

4. A device according to claim 1 wherein at least one of said strap parts is basic and rigidly attached, by means of nails and/or wood screws, to the external surface of femur undertrochanter area.

5. A device according to claim 1 wherein the second of said strap parts is intermediate and rigidly attached, by one its end, by means of said hold-down nut, to the distal end of said osteosynthesis screw, and by its second end rigidly connected with said strap basic part.

6. A device according to claim 5 wherein said strap intermediate part is provided on one its end with a through hole for rigid connection with the distal end of said osteosynthesis screw, said hole having a flare at its distal end the shape of which is opposite to the rounded proximal butt of the respective hold-down or additional nut.

7. A device according to claim 1 wherein said strap consists at least of two parts one of which is basic and the other intermediate, said strap basic and intermediate parts being connected together within a certain range of angular and/or spatial positions by a mechanical joint.

8. A device according to claim 7 wherein said strap basic and intermediate parts are rigidly connected together by a mechanical detachable joint.

9. A device according to claim 8 wherein said basic and intermediate parts of strap are rigidly connected by means of a detachable articulated joint.

10. A device according to claim 7 wherein said basic and intermediate parts of strap are rigidly connected by means of a detachable articulated joint and at least one screw joint.

11. A device according to claim 10 wherein said at least one screw joint is spring-loaded.

12. A device according to claim 8 wherein said basic and intermediate parts of strap are rigidly connected by means of at least two detachable joints.

13. A device according to claim 8 wherein said basic and intermediate parts of strap are rigidly connected by means of a mechanical detachable joint, one of said parts being female, and the other male.

14. A device according to claim 5 wherein said strap intermediate part has in its longitudinal section an S-shape and through longitudinal slot with several holes for fixing said detachable articulated joint.

15. A device according to claim 5 wherein said strap intermediate part has in its longitudinal section an S-shape and at least two through openings on opposite ends for rigid connection of a respective end of strap to the distal end of said osteosynthesis screw.

16. A device according to claim 15 wherein said intermediate part of strap is male, has in its longitudinal section an S-shape, means for fixing in a respective position said detachable articulated joint including several lateral openings, and at least two through holes on opposite ends for rigid connection of the strap to the distal end of said osteosynthesis screw.

17. A device according to claim 15 wherein said basic part of strap is female and has several holes for fixing in a respective position said detachable articulated joint of basic and intermediate parts of strap.

18. A device according to claim 5 wherein said intermediate part of strap has in its longitudinal section a C-shape and a through longitudinal slot which is open from one side and serves for fixing the intermediate part of strap in respective position relative to the basic part of strap.

19. A device according to claim 4 wherein said basic part of strap has holes for connection by means of nails and/or wood screws to the external surface of femur undertrochanter area, said holes being staggered.

20. Osteosynthesis device for holding together in compression the parts of a fractured femur neck, substantially as herein described with reference to the accompanying figures.

ABSTRACT

The invention relates to medicine, and more particularly, to devices applied for osteosynthesis at femur neck fractures. The device comprises a screw formed as a step-shaped rod having a longitudinal axis, a proximal end with a buttress self-tapping thread as well as a distal end with external thread and an internal axial cavity which is provided with internal thread on its distal end and associated with cylindrical external surface of the rod via several longitudinal apertures evenly arranged over this surface, parallel to the generatrix thereof, the outer diameter of the rod distal end corresponds to the outer diameter of the self-tapping thread on its proximal end. There is an antimigration device to fix the screw inside the bone located in the internal axial cavity and comprising a collet chuck with release tabs disposed in apertures, a mechanism for axial reciprocal movement of the collet chuck inside said axial cavity and a mechanism for release tabs operation. The device further includes a hold-down nut located on the rod distal end, at least one extension sleeve and at least one additional nut disposed on external thread of said extension sleeve. The device is provided with an additional strap mounted on the external surface of femur undertrochanter area for treatment of undertrochanter, intertrochanter and transtrochanter lateral femur neck fractures. To suit patients with different anthropometric dimensions of

femur neck, the strap consists at least of two parts rigidly connected with one another within a certain range of angular and/or spatial positions and provided with means for its rigid connection femur undertrochanter area and distal end of said osteosynthesis screw.

20 Claims, 12 Drawing Sheets

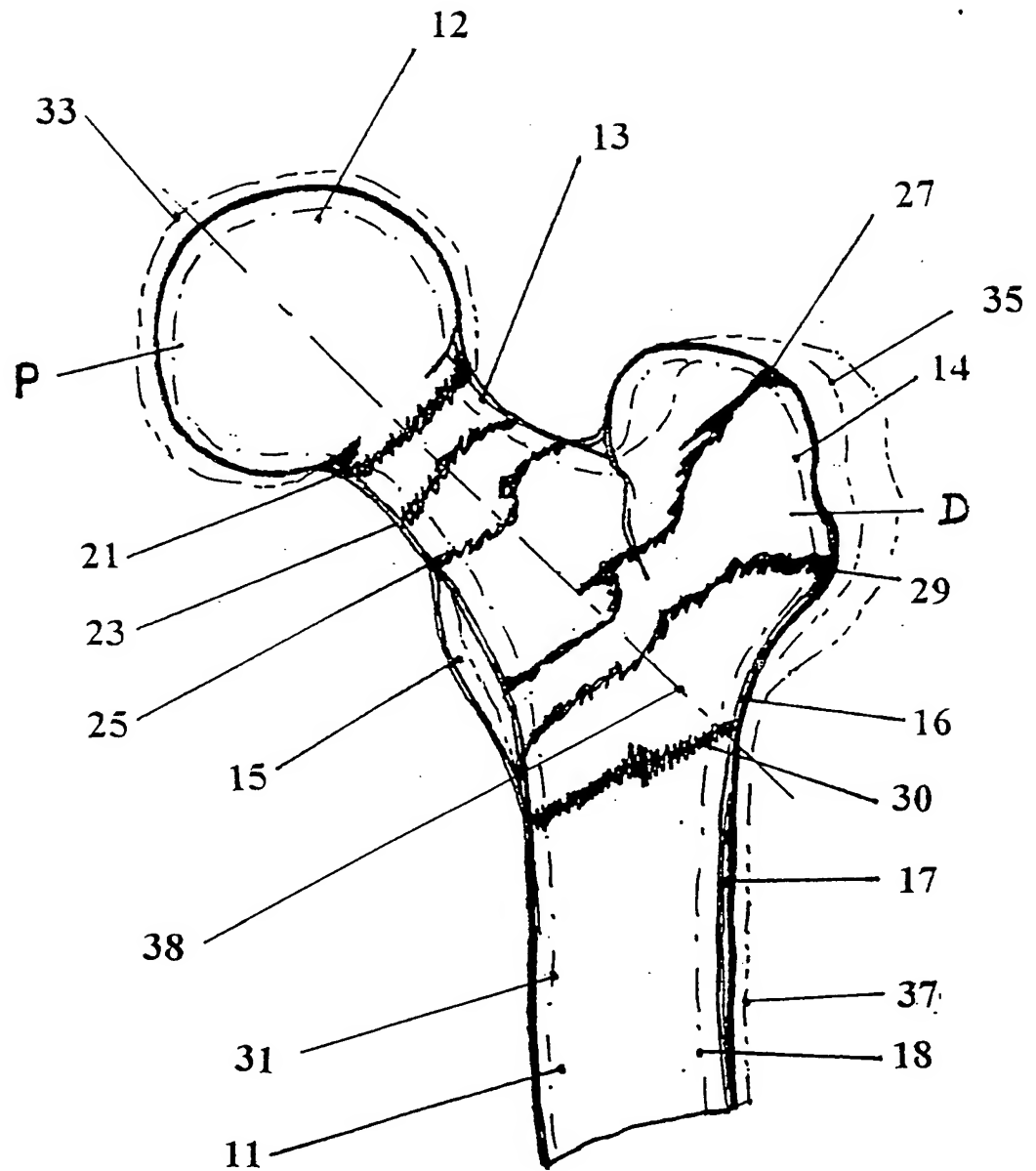
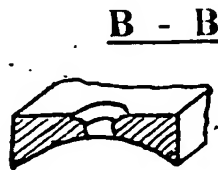
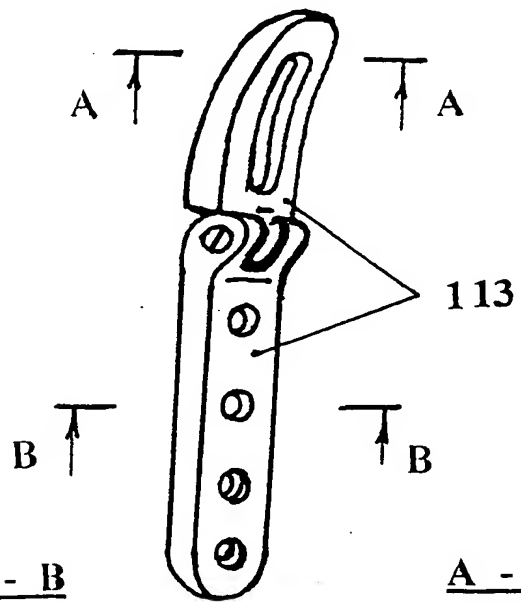
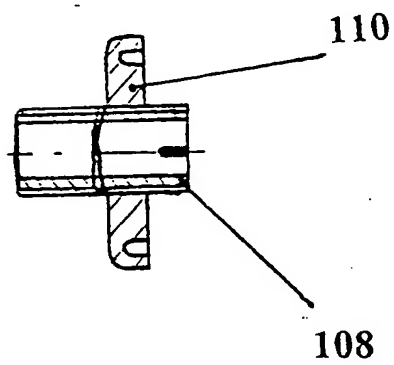
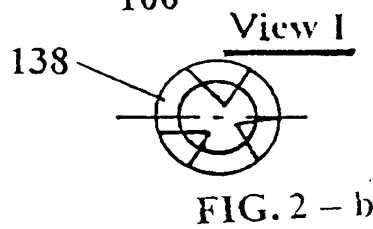
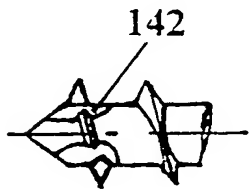
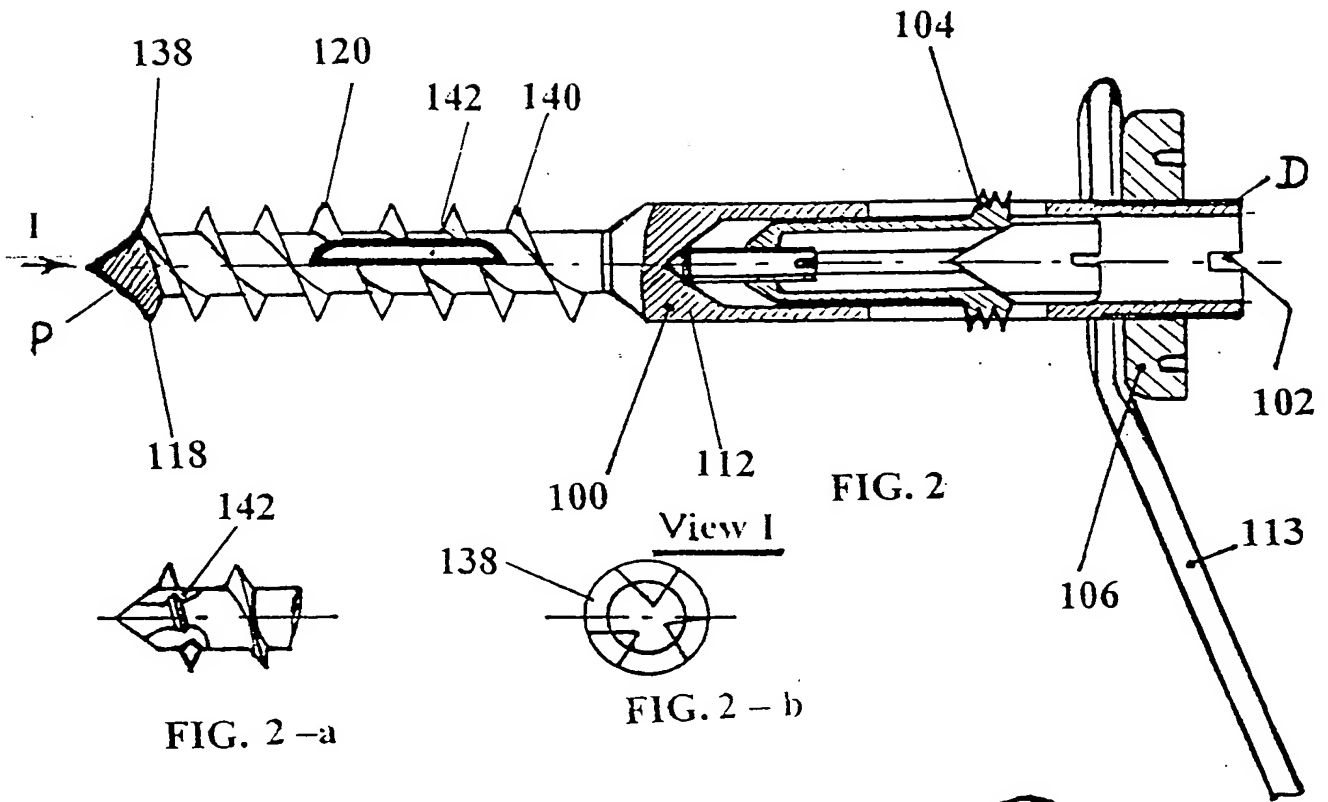


FIG. 1



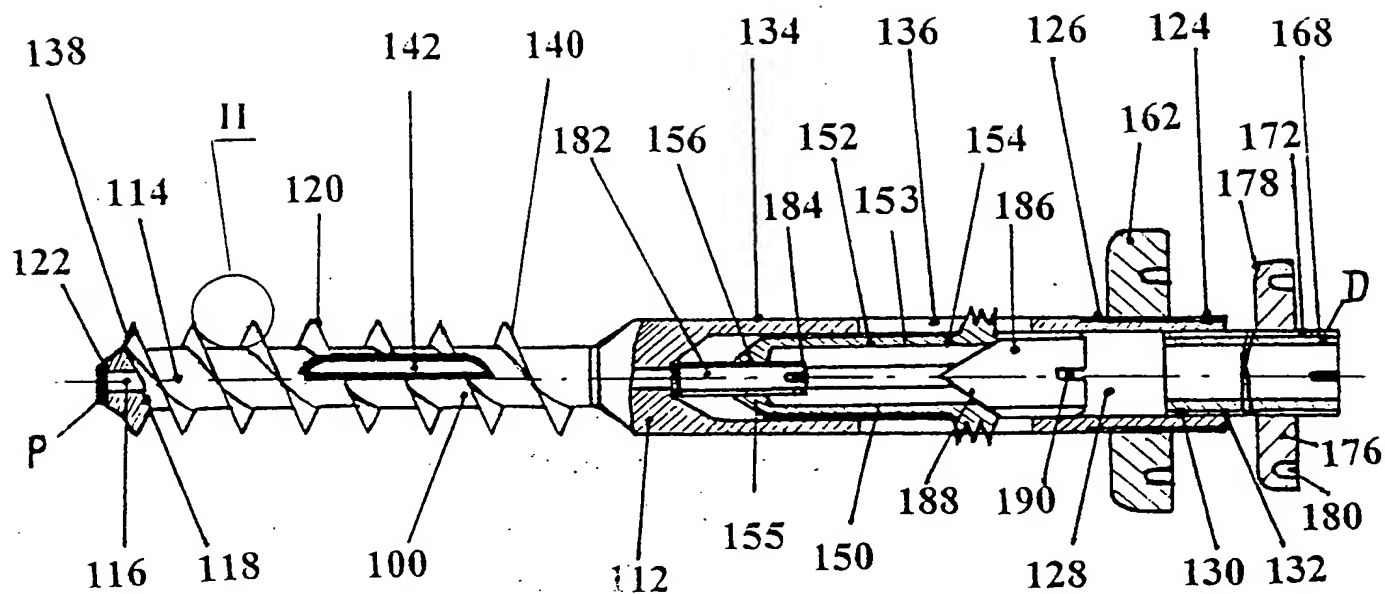


FIG. 4

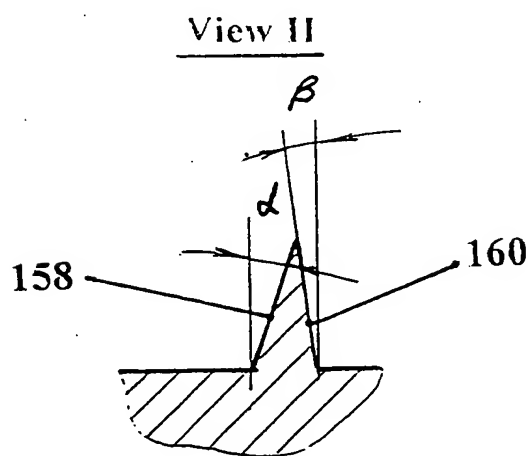


FIG. 5

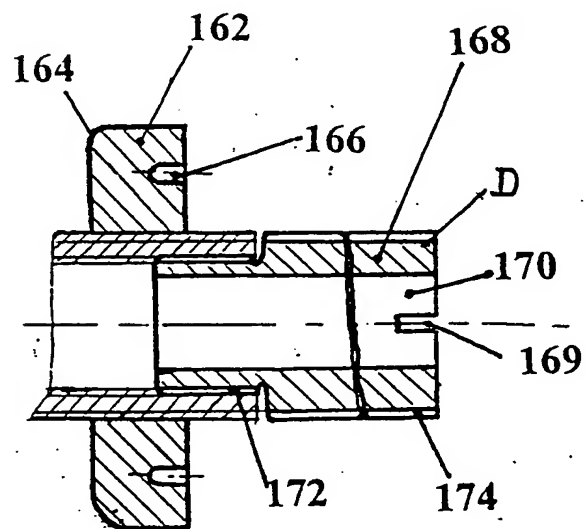


FIG. 6

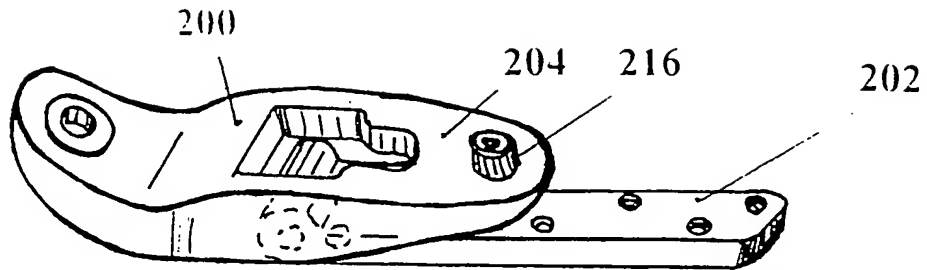


FIG. 7

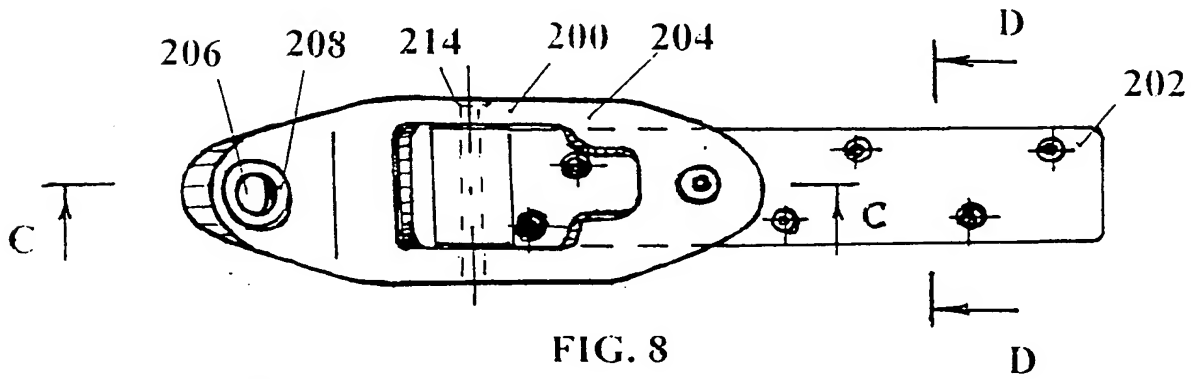


FIG. 8

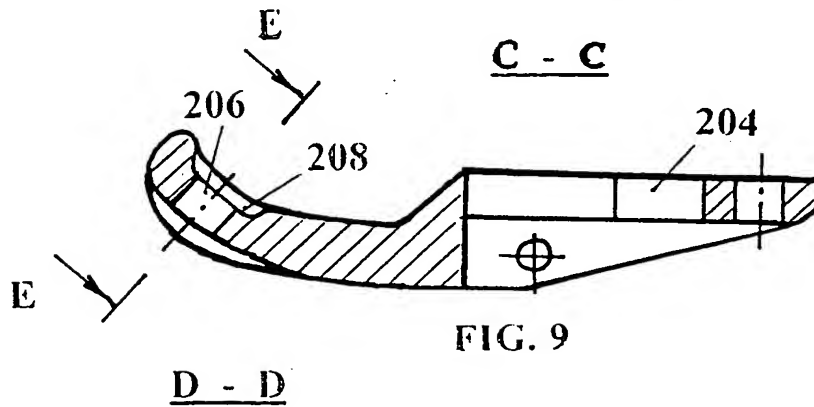


FIG. 9

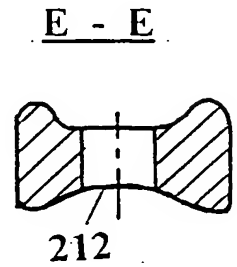


FIG. 12

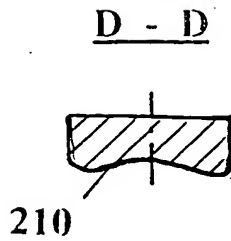


FIG. 11

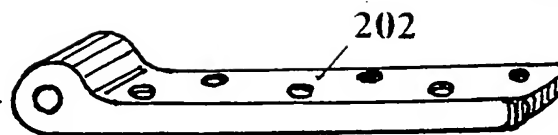


FIG. 10

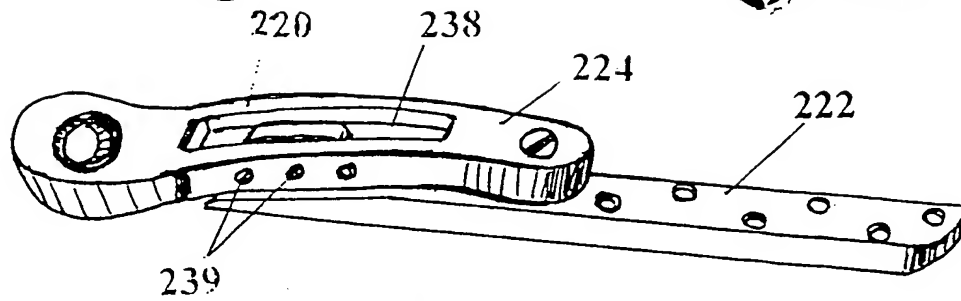


FIG. 13

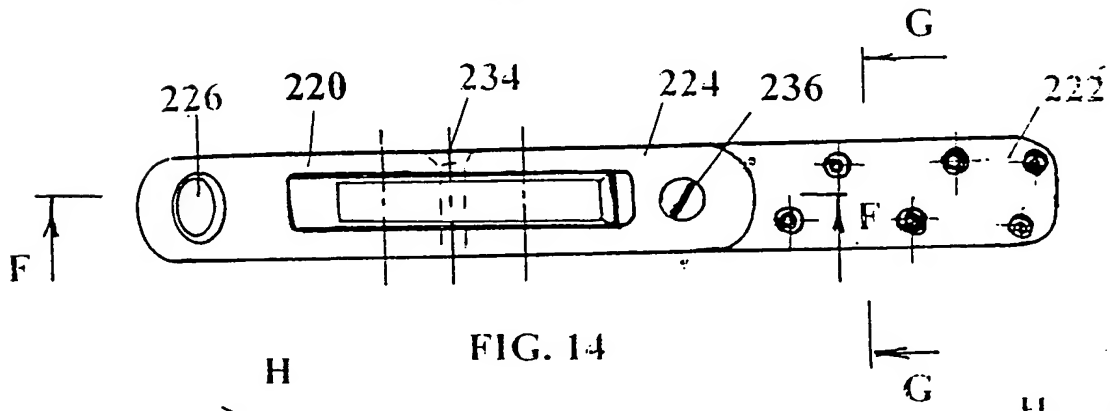


FIG. 14

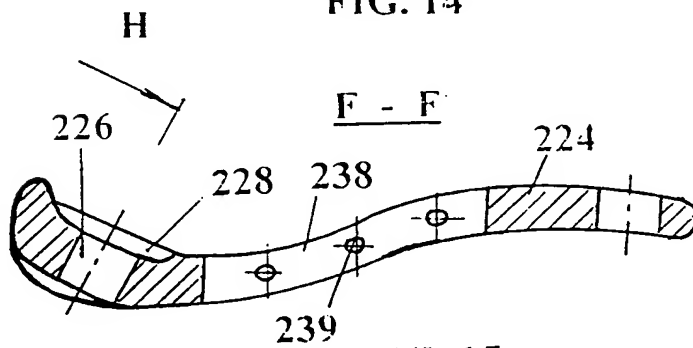


FIG. 15

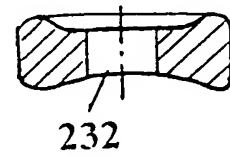


FIG. 18

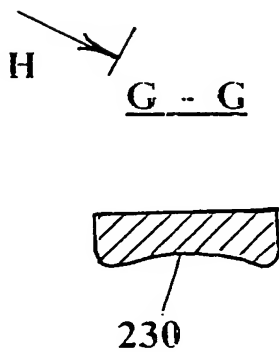


FIG. 17

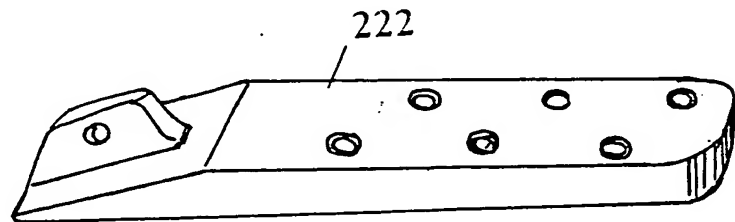


FIG. 16

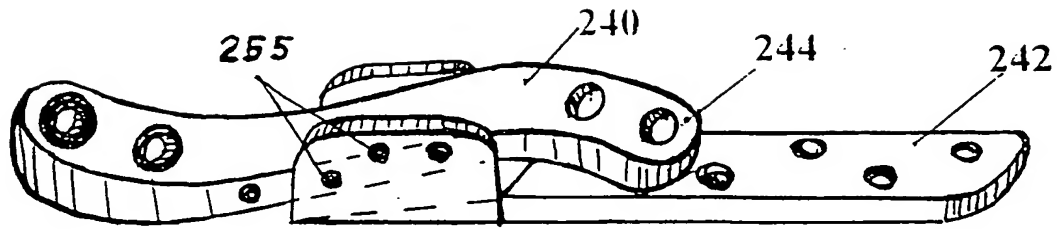


FIG. 19

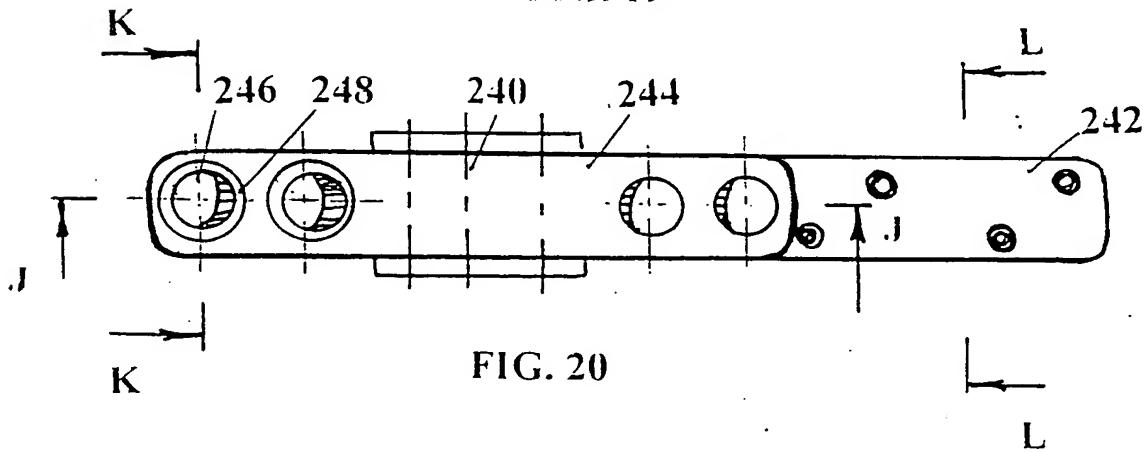


FIG. 20

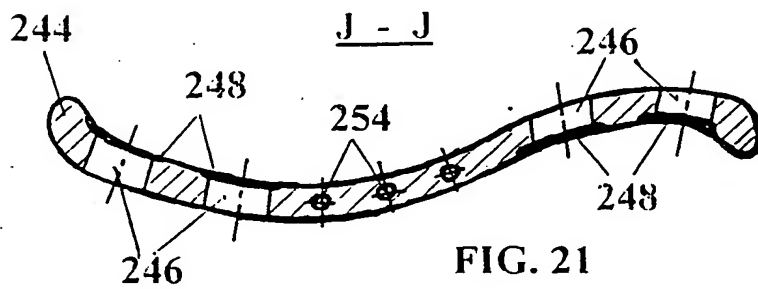


FIG. 21

K - K

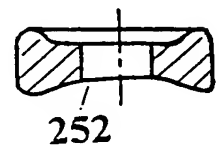


FIG. 23

L - L

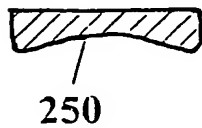


FIG. 24

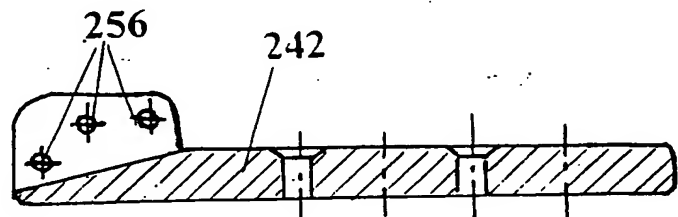


FIG. 22

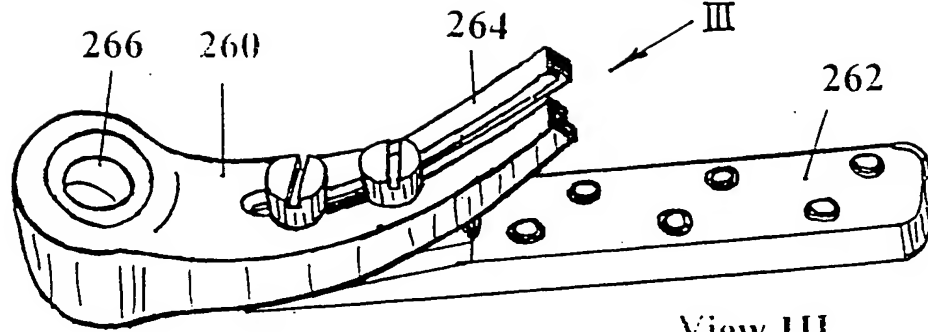


FIG. 25

View III

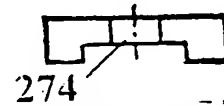


FIG. 26

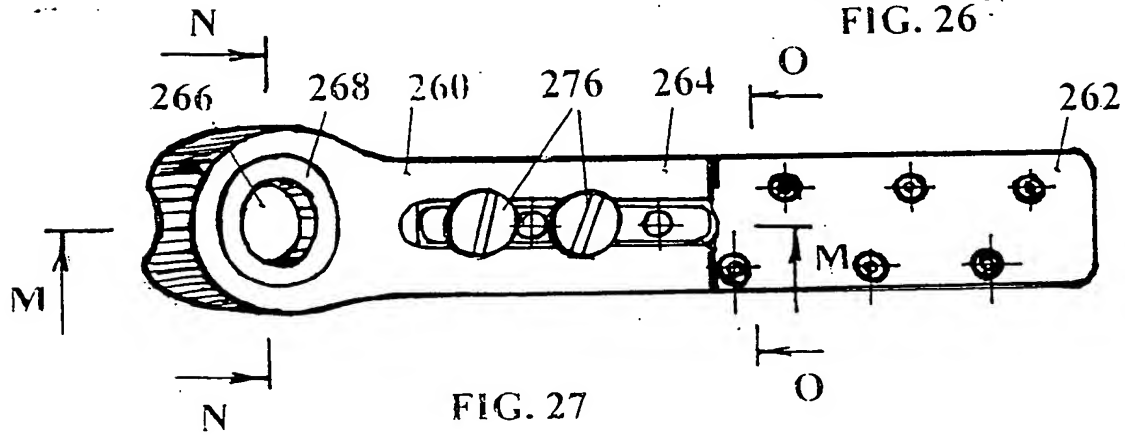


FIG. 27

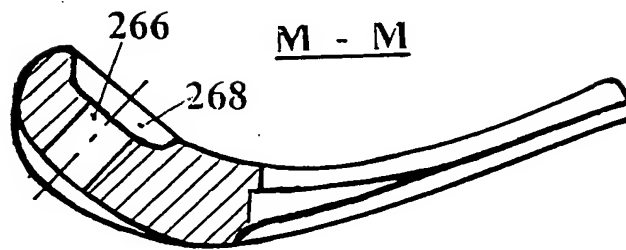


FIG. 28

M - M

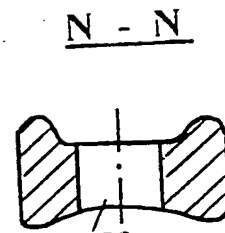


FIG. 30

N - N

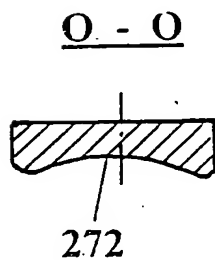


FIG. 31

O - O

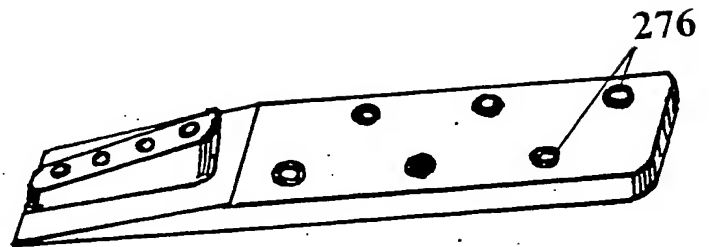


FIG. 29

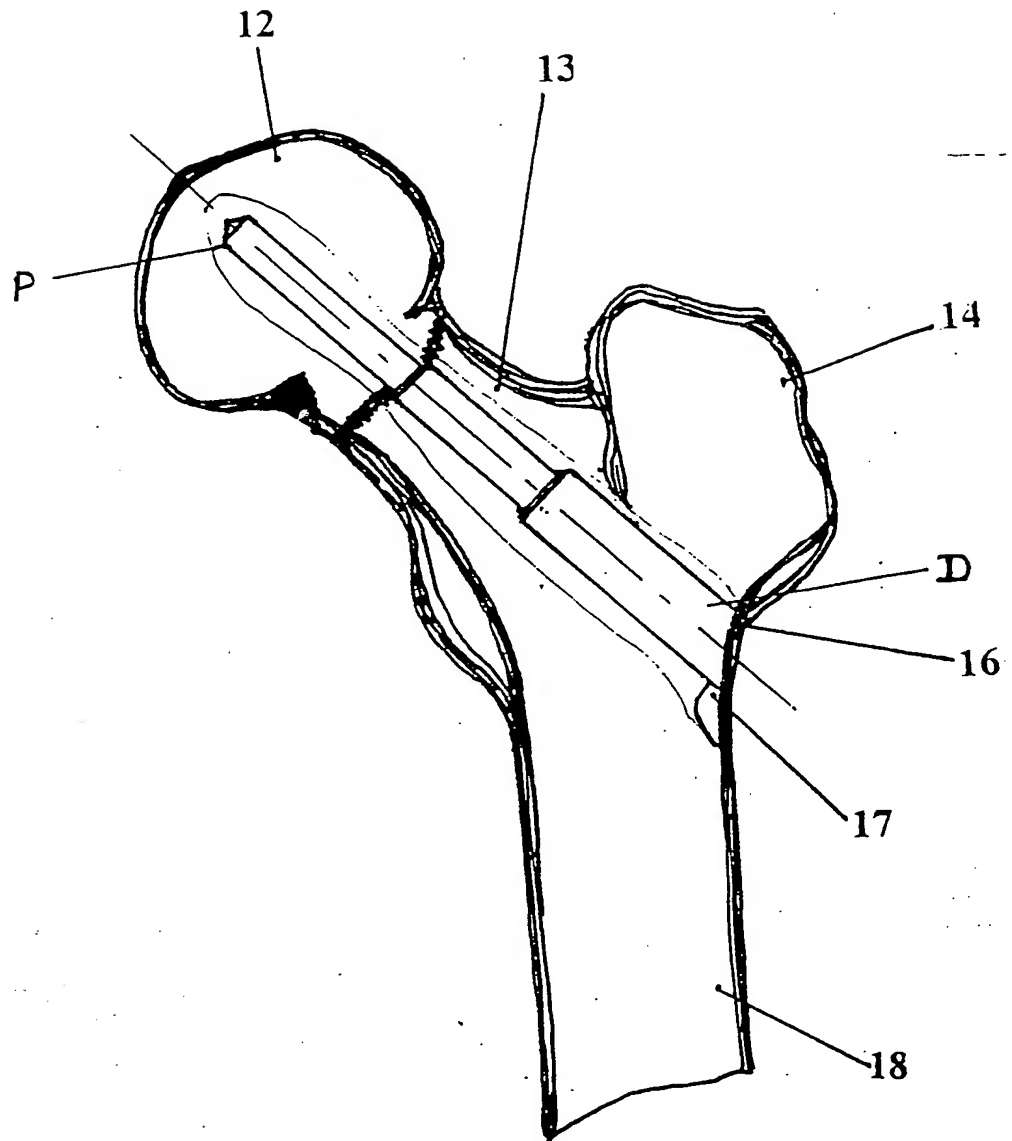


FIG. 32

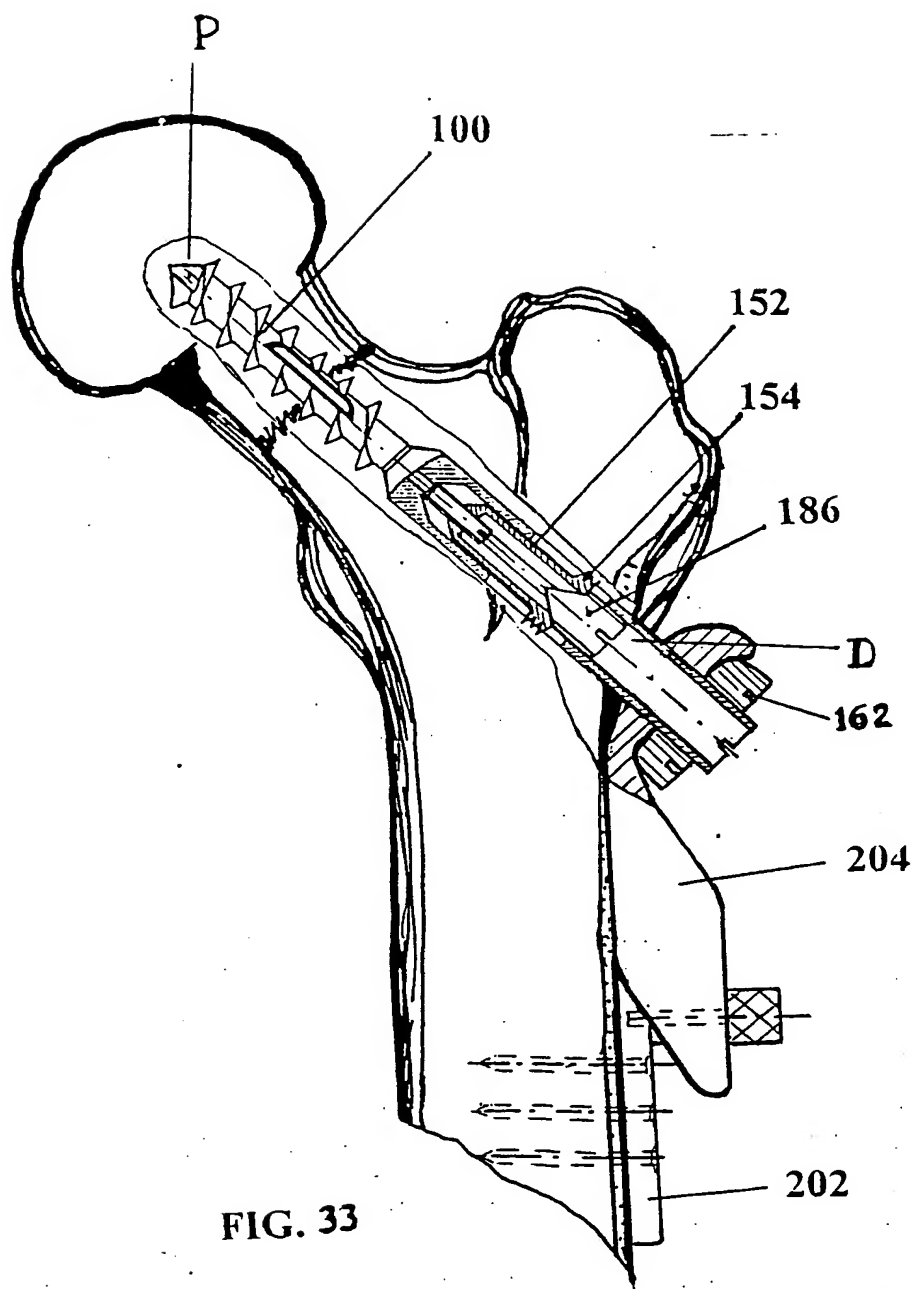


FIG. 33

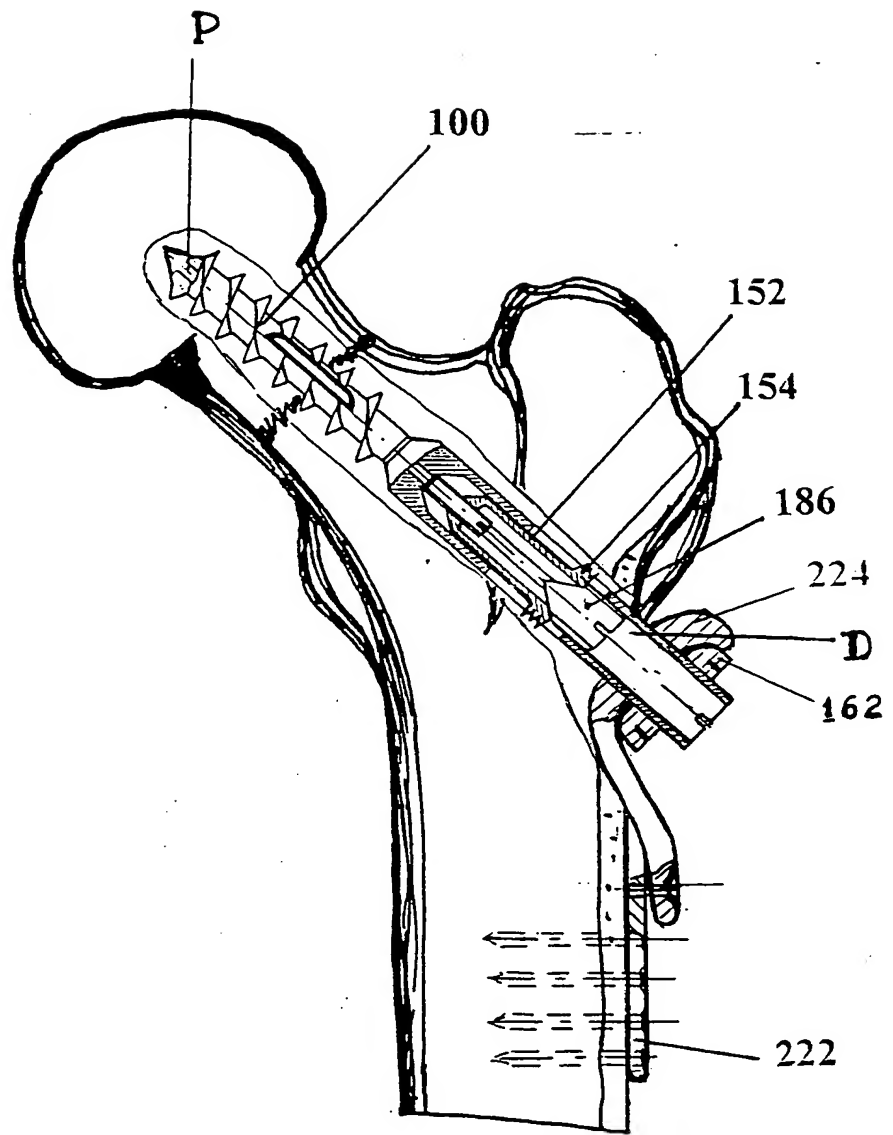


FIG. 34

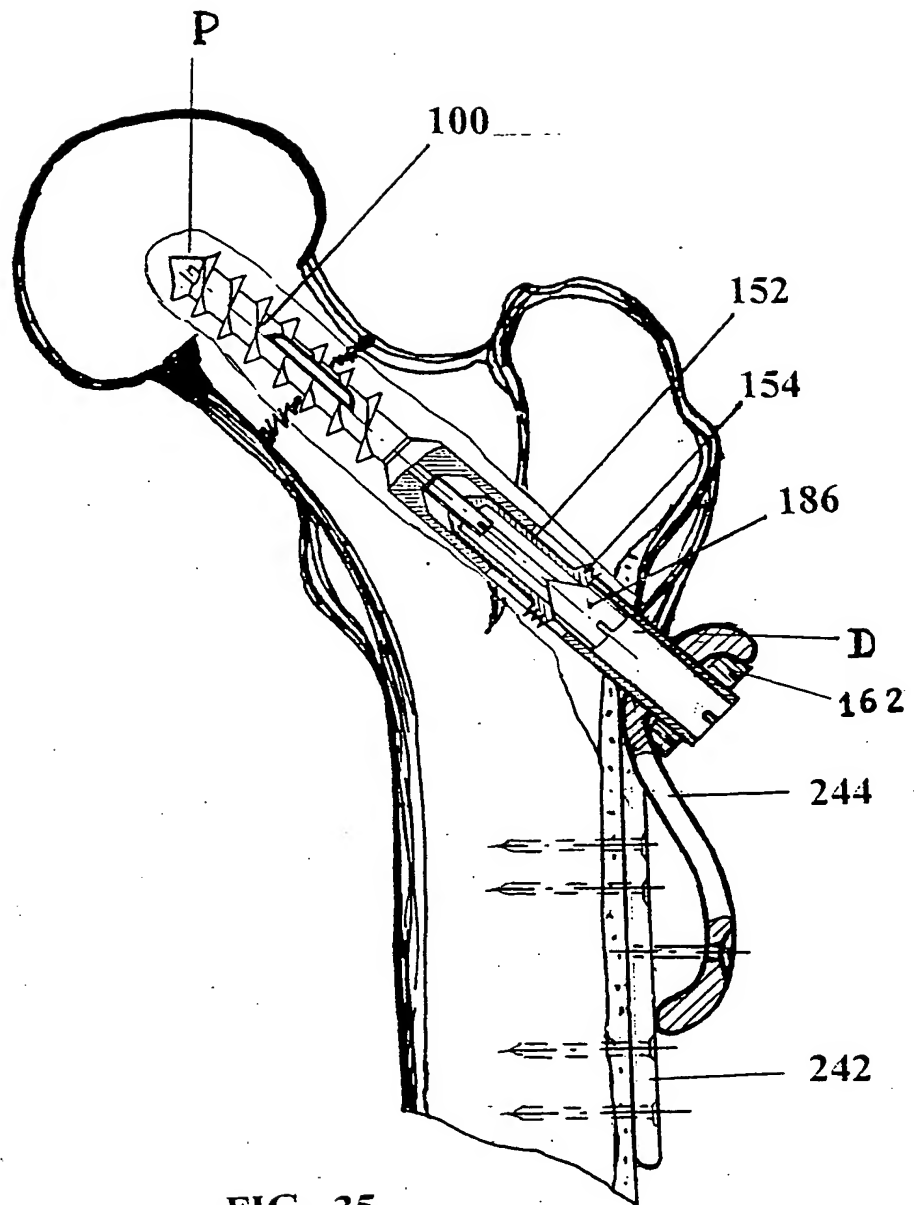


FIG. 35

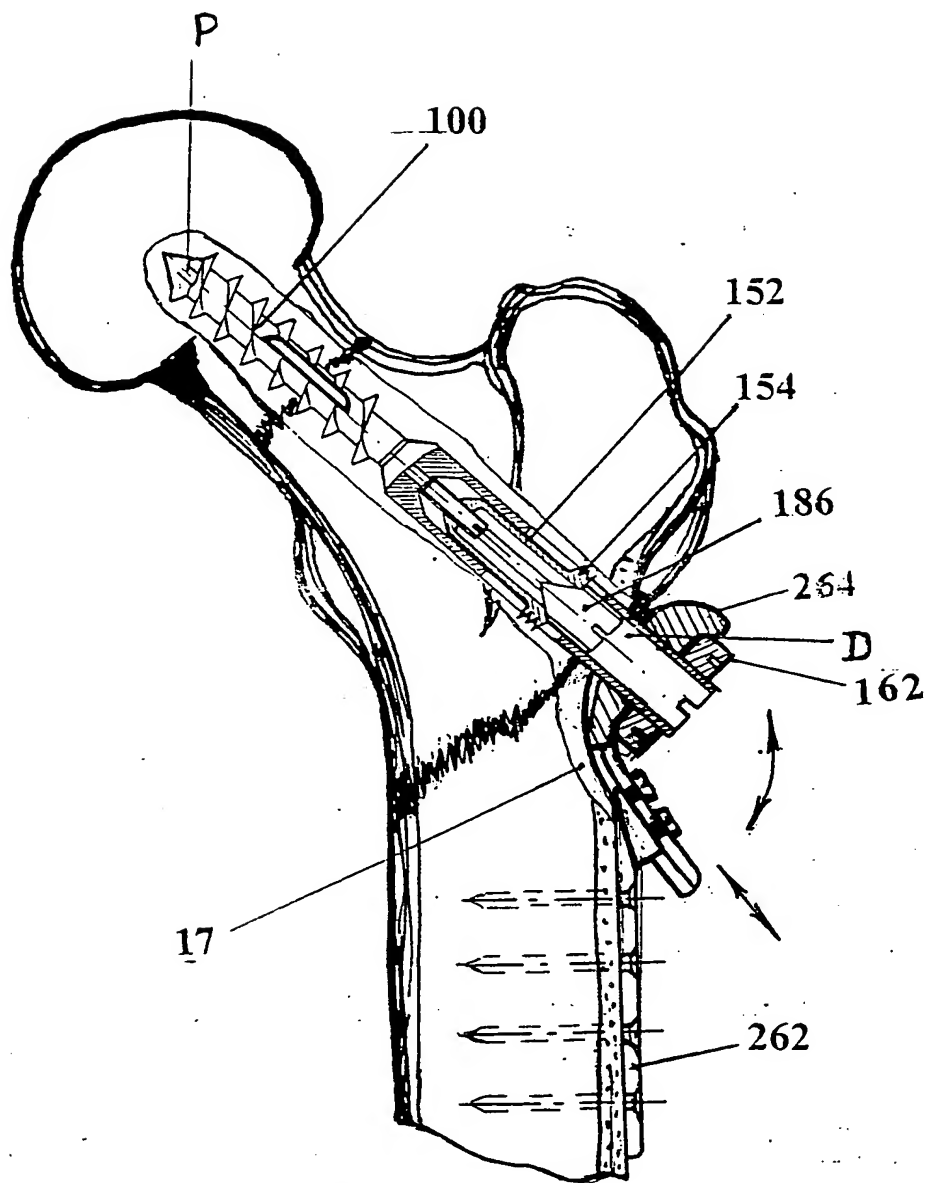


FIG. 36

